

#### REMARKS

Applicant acknowledges receipt of the Office Action mailed March 14, 2008. Applicant has carefully considered all of the rejections raised by the Examiner and responds thereto in detail below. Applicant has amended Claim 21.

##### *Discussion of Rejection of Claim 21*

Claim 21 has been rejected under 102(e) as anticipated by Kroll et al. (US Pat. No. 7,203,550, hereinafter “Kroll”). Applicant respectfully submits that Kroll does not anticipate each and every claim limitation of the amended Claim 21.

The Examiner admits that guiding the migration of certain cell types is not directly taught in Kroll. Instead, the Examiner argues that previous Claim 21 limitation “wherein said variation guides the migration of selected cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies” is a result that is inherent in Kroll. Claim 21 has been amended to recite, “wherein said variation is configured to guide the migration of selected cell types.”

Applicant respectfully submits that the system described by Kroll does not inherently guide the migration of certain cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies. “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” M.P.E.P. § 2112, Sec. IV, 8th Ed., Rev. 5 (citing *In re Rijckaert*, 9 F.3d 1531, 1534, emphasis in original). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.’ ” *Id.* (quoting *In re Robertson*, 169 F.3d 743, 745, emphasis added). Indeed, “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Id.* (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464, emphasis in original).

Kroll teaches a system by which an electrical current is used to destroy bacteria residing in a biofilm of an implanted cardiac treatment device. Kroll, Col 9, lines 45-48. Kroll describes

using an average current density of 150 microamperes per square centimeter to be therapeutic. *Id.*, col. 9, lines 48-52. Kroll notes that an electric current applied at that density could interfere with the heart's conduction, thereby pacing the heart or inducing an arrhythmia. *Id.*, col. 9, lines 52-55. Thus, Kroll teaches varying the current in order to avoid an arrhythmia. For example, Kroll suggests the duration of the electrical current varies according to the heart's refractory period or in a frequency range which is too rapid to affect the heart. *Id.*, col. 9, lines 22-27.

The medical device recited in Claim 21 is directed to varying the surface charge in a manner that controls the migration of certain cell types. Directing the cell migration minimizes fibrous capsule formation and enhances the useful lifetime of the medical device. For example, the electric fields are preferably configured to guide fibroblasts away from the device. As stated in the specification, "fibroblasts in particular have been shown to migrate towards the cathode under the influence of an applied current." Specification, paragraph [0042]. The cathode has the negative bias. Specification, paragraph [0043].

This is different from Kroll. For instance, Kroll Figure 4 shows electric currents 136 and 142 flowing towards the implanted device 120. As a result, fibroblasts would likely migrate towards the implanted device, not away from it. Thus, the Kroll system is actually configured to produce the opposite effect of the present claims.

Furthermore, Kroll fails to teach other factors necessary for using an electric charge to direct the migration of cells, such as the specific frequency of the electric current, as well as other conditions desirable to reduce detrimental side effects. These additional elements are discussed in the Specification paragraphs [0045]-[0057]. Applicant submits that Kroll does not directly or inherently teach a medical device to "configured to guide the migration of selected cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies." Thus, Kroll does not anticipate Claim 21.

Claims 23-27 and 37-47 depend either directly or through another claim from independent Claim 1, and incorporate all the limitations recited therein. Applicant respectfully submits that for at least the above reasons, and their own features, these claims are patentable. Therefore, upon allowance of Claim 21, for at least the reasons discussed herein, Applicant

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respectfully submits that Claims 23-27 and 37-47 are allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

**No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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